Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 21320: Cashew, nutshell liq., polymer with formaldehyde, reaction products with diethanolamine and diisopropanolamine
(Chemical Abstracts Service Registry Number 1462343-28-7)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified chemical is cashew, nutshell liq., polymer with formaldehyde, reaction products with diethanolamine and diisopropanolamine (Chemical Abstracts Service Registry Number[1] 1462343-28-7), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a polyol in the manufacture of polyurethane foams. No other uses are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediment. The substance is not expected to be persistent in these compartments based on its hydrolysis potential. The substance is not expected to bioaccumulate based on its estimated low bioconcentration and bioaccumulation factors (< 250 L/kg).

Environmental risk assessment

1 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on the available hazard information, the substance has moderate acute toxicity to fish (median lethal concentration 10-100 mg/L), moderate acute toxicity to aquatic invertebrates (median effective concentration 10-100 mg/L) and moderate to high chronic toxicity to algae (10% effective concentration (EC_{10}) 0.1-10 mg/L). Using the EC_{10} from the most sensitive organism (algae), and by applying an assessment factor of 5 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from processing from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, which was used to estimate the risk to the environment. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose (LD_{50}) > 2000 mg/kg body weight) and dermal route (LD_{50} > 1000 mg/kg -bw), with no adverse effects indicative of potential mortality at the highest dose tested), and moderate subchronic toxicity following repeated dermal doses in mammalian test animals (28-day no-observed-adverse-effect level 60-600 mg/kg-bw/day). It is not a dermal sensitizer (0% response in a Buehler test). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in the manufacture of polyurethane foams, direct exposure of the general population is not expected due to the commercial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized commercial use of the substance, which results in little or no release to the environment. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.